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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,516	03/17/2004	Stewart Loh	RFSUNY-3681 R1407	3967

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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/802,516	Applicant(s) LOH ET AL.	
	Examiner Pablo Whaley	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CLAIMS UNDER EXAMINATION

Claims herein under examination are 1-6 and 8-11. Claims 7 and 12 have been cancelled.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied, as necessitated by amendment. They constitute the complete set presently being applied to the instant application.

OBJECTIONS

The disclosure is again objected to because of the following informalities: (i) While the specification has been amended [p.39], the "Detailed description of the invention" does not include a description for element #25 as shown in Fig. 1B, therefore it cannot be determined what element #25 is intended to be. Appropriate correction is required.

LACK OF UTILITY

Claims 1-6 and 8-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well-established utility.

In the instant case, the claimed invention is not supported by a well-established utility. The instant claims generally recite a mutually exclusive folding domain molecular switch comprising a fusion protein and a target protein. The specification discloses several general disciplines where the instant invention may be “useful” for pharmacologic agents in the treatment of cancer [p.1] and in developing diagnostic and therapeutic proteins with novel capabilities [p.4 and p.14]. However, these utilities are not specific to the instant claims. Furthermore, the specification discloses the regulatory domain of ubiquitin and the catalytic domain of barnase cannot simultaneously co-exist in their folded states [p.23, ¶ 4], and the regulatory domain of ubiquitin can be used to regulate the cytotoxic activity of barnase [p.23, ¶ 4]. However, these utilities are not specific to the instant claims [See 112 2nd rejection below]. For these reasons, the claimed subject matter does not have a specific, substantial, and credible utility.

Claims 1-6 and 8-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. This rejection is necessitated by amendment.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments [p.10], filed 07/20/2006, that point to the specification for a definition of the term "surface loop" do not clarify the conflicting claim language as it pertains to the terms "surface loop" and "surface loop amino acid." Therefore the following rejection is reiterated. Claim 1 recites the limitation "a first surface loop" (line 5). Claim 1 later recites a "first surface loop amino acid" (line 6), therefore it is unclear whether the "first surface loop" and "first surface loop amino acid" are in fact the same thing or distinct elements of the invention. Clarification is requested.

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Amended claim 1 is now directed to a "mutually exclusive folding domain molecular switch." It is unclear as to the intended meaning of a "folding domain molecular switch." Furthermore, it is unclear what elements of the "molecular switch" are intended to be "mutually exclusive" (e.g. regulatory domains, folding domains, fusion proteins, target proteins, etc.). It is noted that the specification [p.23] discloses regulatory domains that cannot co-exist. If applicant's intend for "regulatory regions" to be mutually exclusive, the claims should clearly recite this limitation. Clarification is requested.

Amended claim 1 now recites the limitation "comprising a regulatory domain of ubiquitin lying between..." (lines 3-4). It is unclear whether the said "regulatory domain" lies anywhere between the amino terminus and the carboxy terminus, in a specific location, or otherwise. Clarification is requested. Claims 3-6, 8, 9, and 10-11 are rejected as they depend either directly or indirectly from claim 1.

CONCLUSION

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

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